

Notice of Allowability

Application No.

09/484,886

Examiner

Dr. Kailash C. Srivastava

Applicant(s)

SMITH ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 15 March 2005.
2. ☒ The allowed claim(s) is/are 96-116.
3. ☒ The drawings filed on 18 January 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 15.3.2005.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Examiner's Amendment/ Comments

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 CFR §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Ms. Angela M. Collison on 16 March 2005.

TITLE:

Replace the existing title with the following title:

--*In vivo* Active Erythropoietin Produced in Insect Cells--.

IN THE ABSTRACT:

Replace the existing Abstract with the following:

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Disclosed and claimed is a human erythropoietin (EPO) expressed and produced in *Spodoptera frugiperda* Sf900+ cell line (ATCC: CRL 12579) transfected with a baculovirus construct containing the EPO gene. The EPO has an *in vivo* activity of 200,000 U/mg to 500,000 U/mg.

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2. The following is Examiner's statement of reasons for allowance:

The closest prior art are: Quelle et al. (Quelle, F. W. et al. 1989. Blood, Volume 74, Pgs. 652-657), Wojchowaki et al. (Wojchowski, D.M. et al. 1987, Biochimica et Biophysica Acta, Volume 910, Pages 224-232), U. S. Patents issued to Smith et al. (U.S. Patents 5,762,939; 5,858,368; 6,103,526 and 6,245,532) and to Chao (6,245,532). Quelle et al. and Wojchowki et al. have obtained a human erythropoietin (EPO) expressed and produced in *Spodoptera frugiperda* cell line transfected with a baculovirus construct containing the EPO gene, however their EPO is not active *in vivo*.

ATCC catalog lists only *Spodoptera frugiperda* Sf9 cell line.

Smith et al. (U.S. Patent 6,103,526) disclose a variety of recombinant proteins (e.g., HA, NA, EPO, CD4, CEA and thrombospondin) from recombinant baculovirus expression in *Spodoptera frugiperda* Sf900+ cell line (See abstract), but do not claim the EPO claimed in instant application. This patent shares all three of the instant inventors and is therefore not derived from another – the disclosure of EPO in the instant application is identical to the patent having been incorporated by reference therefrom.

U.S. Patents 5,762,939; 5,858,368; 5,911,982 and 6,245,532 are not drawn to production of EPO but other proteins via baculovirus expression in *Spodoptera frugiperda* Sf900+ insect cells.

Thus, none of the art cited *supra* alone or in combination teach or reasonably suggest to obtain a human erythropoietin (EPO) expressed and produced in *Spodoptera frugiperda* Sf900+ cell line (ATCC: CRL 12579) transfected with a baculovirus construct containing the EPO gene, wherein said recombinant EPO has an *in vivo* activity of 200,000 U/mg to 500,000 U/mg.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 96-116 are allowed.

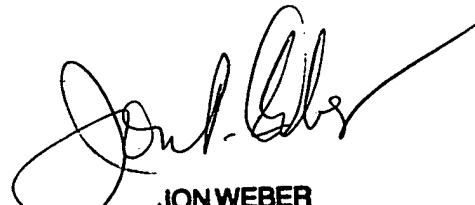
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571)-272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

March 17, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER